

8. PREMARKET NOTIFICATION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR CURING LIGHT LED Turbo-Pen

(family: LED Turbo-Pen, TOP Light, TOP Light PLUS,
TOP Light Turbo)

JUN 18 2004

K04 1303

8.1 Submitter's name: APOZA ENTERPRISE CO., LTD.

8.2 Address: 6F, 657, Chung-Cheng Road, Hsin-Chuang City,
242 Taipei Hsien, Taiwan, ROC.

8.3 Phone No:886-2-29010620

8.4 Fax No:886-2-29012208

8.5 Contact person: Mr. Shin Min Teh

8.6 Date prepare: Apr 1, 2004

8.7 Trade name/proprietary name: LED Turbo-Pen

(family: LED Turbo-Pen, TOP Light, TOP Light PLUS, TOP Light Turbo)

8.8 Common name/usual name: Dental Curing Light

8.9 Classification name: Ultraviolet dental curing light.

TRADE NAME	COMMON NAME	CLASSIFICATION NAME
LED Turbo-Pen (family: LED Turbo-Pen, TOP Light, TOP Light PLUS, TOP Light Turbo)	Dental curing light	Ultraviolet activator for polymerization

8.10 Legally market device equivalence:

Device name: Led Turbo

510k number: K040618

Manufacturer: APOZA Enterprise, Co.,Ltd.

8.11 Intended use:

The LED Turbo-Pen is a dental curing light that is designed for use in the optic polymerization of dental resins.

8.12 Device description

The LED Turbo-Pen consists of a handy unit and a battery charger. The handy unit contains a programmed control circuit, high intensity dental blue LED light source, a light guide and a optical fiber that conduct light to the treatment area on the patient. The control circuit which governs the output power rate, timing and monitoring the temperature of the LED.

8.14 Comparison with equivalence marketed device:

	LED Turbo-Pen	Led Turbo
1. Light Intensity	500~1600mW/cm ²	1600mW/cm ²
2. Output Wave length	440nm~490nm	440nm~490nm
3. LED power consumption	1 Watt and 5 Watt	5 Watt
4. Battery use	7.2V/1900mAh	7.2V/1900mAh
5. Operating Voltage	AC100V~260V 50/60Hz	AC100V~260V 50/60Hz
6. Curing time	5, 10, 20, 40 seconds selectable	5, 10, 20, 40 seconds selectable

Both the LED Turbo-Pen and the predicate curing lights offer multiple curing programs for photopolymerization of dental resins and activation of bleaching materials. These programs differ in the intensity of the light delivered and the length of the light exposure. The operational principles of the proposed and predicate devices are identical. The operator chooses the appropriate program and sets the treatment parameters, if necessary. The tip of handpiece is oriented appropriately relative to the material being photopolymerized, or the tooth surface (for bleaching procedures), and the selected treatment is initiated.

The major difference between the proposed LED Turbo-Pen and the predicate curing lights is the intensity of the light power delivered. The increased light intensity of the proposed LED Turbo-Pen allows the resin curing and tooth whitening agent activation to be conducted in a much shorter timeframe. Performance testing has been conducted that confirms that the halogen light technology used for LED Turbo-Pen is able to cure resin and activate tooth bleaching agents within the specified timeframe without causing thermal damage to the tissue.

The Similarities in intended use, technical specifications, and functional performance between the LED Turbo-Pen and LED Turbo to a conclusion of substantial equivalence between the proposed and predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2004

Mr. Shin Min-Teh
General Manager
Apoza Enterprise Company, LTD
6F, 657, Chung-Cheng Road
Hsin-Chuang City, Taipei Hsien, 242
Taiwan, CHINA

Re: K041303
Trade/Device Name: LED Turbo-Pen
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: May 01, 2004
Received: May 17, 2004

Dear Mr. Min-Teh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041303

Device Name: LED Turbo-Pen

Indications for Use:

The LED Turbo-Pen is a dental curing light that is designed for use in the optical polymerization of dental resins.

Prescription Use X
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041303

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